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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/864,761

05/23/2001

Sharron Gaynor Penn

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10/30/2002

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EXAMINER

LY, CHEYNE D

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 10/30/2002

10

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/864,761	Applicant(s) PENN ET AL.	
	Examiner Cheyne D Ly	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-58 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-58 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

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|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) Paper No(s). <u>9</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)                |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other:   |

### **DETAILED ACTION**

1. This Office Action is a response to the telephone request by the Applicant on October 9, 2002 for a written Restriction Office Action.
2. This Office Action is a modification of the Office Action, Paper No. 6, mailed on June 24, 2002. Upon further examination, the examiner has elected to re-restrict all of the claims.
3. Applicant is notified that an Examination Interview Summary dated October 09, 2002 is attached.

### ***Election/Restrictions***

4. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-32 and 48, drawn to a single nucleic probe, classified in class 536, subclass 23.1. If this Group is elected, then the below summarized sequence election is required.
  - II. Claims 33-39, drawn to a set of single exon nucleic acid probes, classified in class 536, subclass 23.1. If this Group is elected, then the below summarized sequence election of two SEQ ID NOS is required. If this Group is elected, then the below summarized specie election is also required.
  - III. Claims 40-44, drawn to single exon microarray, classified in class 435, subclass 287.2. If this Group is elected, then the below summarized sequence election of two SEQ ID NOS is required.
  - IV. Claims 45-47, drawn to a method of measuring human gene expression, classified in class 435, subclass 6. If this Group is elected, then the below summarized sequence election of two SEQ ID NOS is required.

- V. Claims 49-50, drawn to polypeptides, classified in class 530, subclass 350. If this Group is elected, then the below summarized sequence election is required.
- VI. Claim 51, drawn to antibodies, classified in class 530, subclass 387.1. If this Group is elected, then the below summarized sequence election is required.
- VII. Claims 52-57, drawn to the system and the method of selling and/or licensing probes or microarrays and method of providing human gene expression data by subscription, classified in classes D14 and 705, subclasses 300 and 1, respectively. If this Group is elected, then the below summarized sequence election of two SEQ ID NOS is required. If this Group is elected, then the below summarized specie election is also required.
- VIII. Claim 58, drawn to a method of financing a company that makes and sells single exon probes, single exon microarrays, or expression data, classified in class 705, subclass 35. If this Group is elected, then the below summarized sequence election is required. If this Group is elected, then the below summarized specie election is also required.

**Sequence Election Requirement Applicable to All Groups:**

In addition, each Group detailed above reads on patentably distinct sequences. Each sequence is patentably distinct because they are unrelated sequences, and a further restriction is applied to each Group. For an elected Group drawn to amino acid/polypeptide sequence, the Applicants must further elect a single amino acid/polypeptide sequence. For an elected Group drawn to nucleotide sequences, the Applicants must elect a single nucleic sequence (See MPEP § 803.04). For Groups II, III, IV, or VII drawn to a set nucleotide sequences, the Applicant may

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elect two SEQ ID NOS for one of these elected Groups. It is noted that the multiple of sequence submissions for examination has resulted in an undue search burden if more than one nucleic acid sequence is elected, thus making the previous waiver for up to 10 elected nucleic sequences effectively impossible to reasonably implement.

MPEP § 803.04 states:

Nucleotides sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions with the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq. Examination will be restricted to only the elected sequence. It is additionally noted that this sequence election requirement is a restriction and not a specie election requirement.

#### **SPECIE ELECTION REQUIREMENT FOR GROUP II :**

2. This application contains claims directed to the following patentably distinct species of the claimed invention:

Specie A: Probe set immobilized on a substrate or microarray

Specie B: Probe set not immobilized on a substrate or microarray

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 33-39 are generic. These species are distinct due to the distinct use of each. Individually, these distinct species are used in various methods for the sequencing

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or determine gene expression. For example, probes that are not immobilized may be used for *in situ* hybridization while immobilized probes may be used for microarray analysis.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

#### **SPECIE ELECTION REQUIREMENT FOR GROUP VII:**

2. This application contains claims directed to the following patentably distinct species of the claimed invention:

Specie A: Microarray available for sale/licensing along with database access

Specie B: No microarray availability for sale/licensing along with database access

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 52-57 are generic. These species are distinct due to the distinct means of selling/licensing microarray.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

#### **SPECIE ELECTION REQUIREMENT FOR GROUP VIII:**

2. This application contains claims directed to the following patentably distinct species of the claimed invention:

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Specie A: At least single exon probes are available for distribution, sale, and/or license.

Also, two sequence SEQ ID NOS may be chosen if this specie is elected.

Specie B: At least single exon microarrays are available for distribution, sale, and/or license. Also, two sequence SEQ ID NOS may be chosen if this specie is elected.

Specie C: At least data from the above species A and/or B are available for distribution, sale, or license. Also, two sequence SEQ ID NOS may be chosen if this specie is elected.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Further, the Applicant may elect two SEQ ID NOS for each species elected. Currently, claim 58 is generic. These species are distinct due to the distinct products for each type of transaction.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).



Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups [I, II, and IV]; [III]; [V]; [VI]; [VII]; [VIII] are distinct inventions because they are directed to different chemical or entity types regarding the critical limitations therein. For Groups I, II, and IV, the critical feature is a nucleic acid molecule. For Group III, the critical feature is a microarray apparatus. For Group V, the critical feature is a polypeptide. For Group VI, the critical feature is an antibody. For Group VII, the critical feature is a system and method for selling and/or licensing probes or microarrays or human gene expression data. For Group VIII, the critical feature is a method for financing a company that makes and sells single exon probes, single exon microarrays, or expression data. Further, it is acknowledge that various processing steps may cause a peptide of Groups V to be directed as to its synthesis by a polynucleotide set forth in of Group I, however, the completely separate chemical and entity types of the inventions of the polynucleotide and polypeptide support the undue search burden if they were examined together. Additionally, polypeptide, antibodies, microarrays, systems and business methods have been most commonly, albeit not always, separately characterized and published in the Biochemical literature, thus significantly adding to the search burden if examined together as compared to being search separately. Also, it is pointed out that processing

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that may connect two Groups does not prevent them from being viewed as distinct because enough processing can result in producing any composition from any other composition if the processing is not limited as to additions, subtractions, enzyme action, etc. Thus, the six Groupings: Groups [I, II, and IV]; [III]; [V]; [VI]; [VII]; and [VIII] are independent and/or distinct invention types for restriction purposes.

Inventions in Groups I, II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case of human genome-derived single exon nucleic acid probes useful for gene expression analysis, nucleic acid molecule of Group I may be utilized in the distinct usages as a set of probes. As needed in Group IV, which is a method for measuring human gene expression, or alternatively, as an antisense therapy. All of these usages are distinct as requiring distinct and different functions and results thereof without overlapping search due to different subject matter. This lack of overlapping searches documents the undue search burden if they were search together.


6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

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8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).
9. Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (see 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (703) 308-3880. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.
11. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.
12. Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

C. Dune Ly  
10/28/02

  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER